Dietary Risk Assessment
Ortho phenyl phenol : case study

JIFSAN Training

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Overview

- Risk Assessment Overview
- Dietary Assessment Techniques
- Ortho phenyl phenol case example
- Choosing the relevant population
- Choosing the relevant toxicological data
- Risk Assessment
- Summary

Risk Assessment seeks to answer three questions

- What can go wrong?
- How likely is it to happen?
- What are the consequences if it does happen?

Risk Assessment

Risk = probability of an adverse outcome resulting from exposure to a particular hazard – or suite of hazards – by the population of interest

Hazard = substance or object that causes a undesirable effect on health or the environment

Exposure = contact by the population of interest with the hazard

Risk = ƒ(duration and intensity of exposure to hazard & susceptibility)

There is no cookbook of risk assessment recipes

You must consider each risk assessment problem on a case-by-case basis

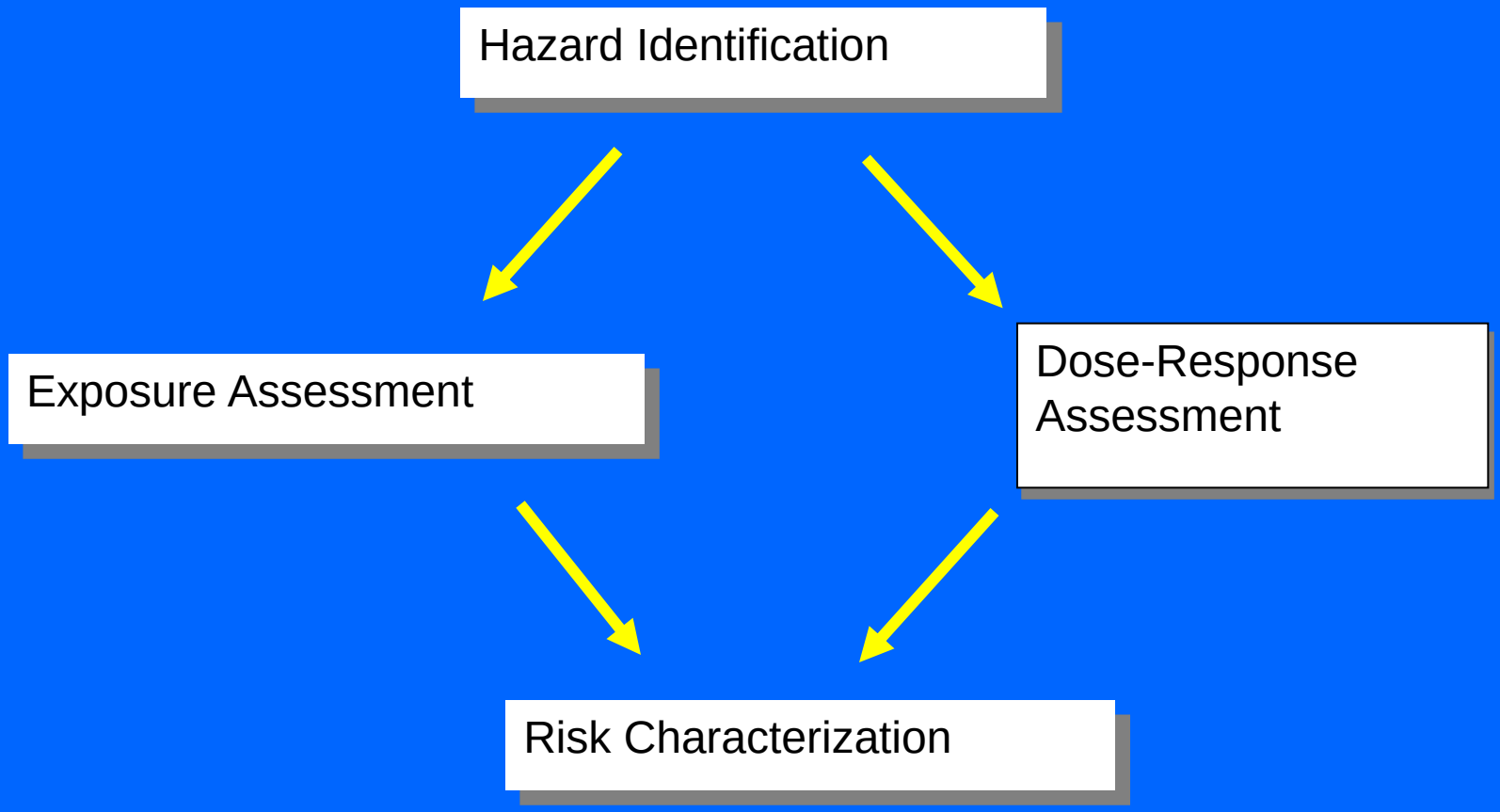
RISK ASSESSMENT FRAMEWORKS

Classic Risk Assessment Efforts by the National Academy of Sciences

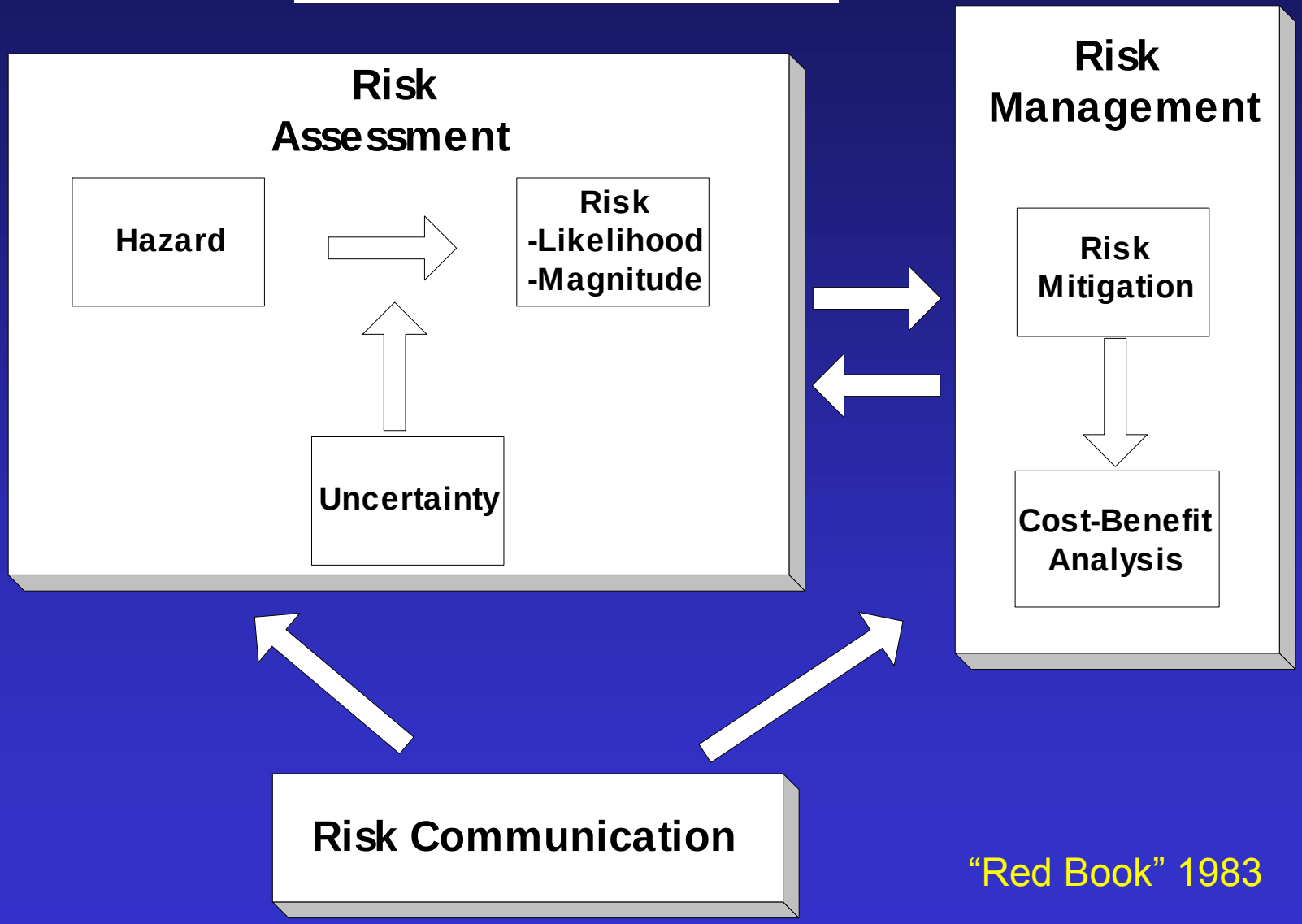
National Research Council 1983 "Red Book"
Risk Assessment in the Federal Government: Managing the Process

National Research Council 1994
Science and Judgment in Risk Assessment
"Orange Book"

"Red Book" Risk Assessment Process

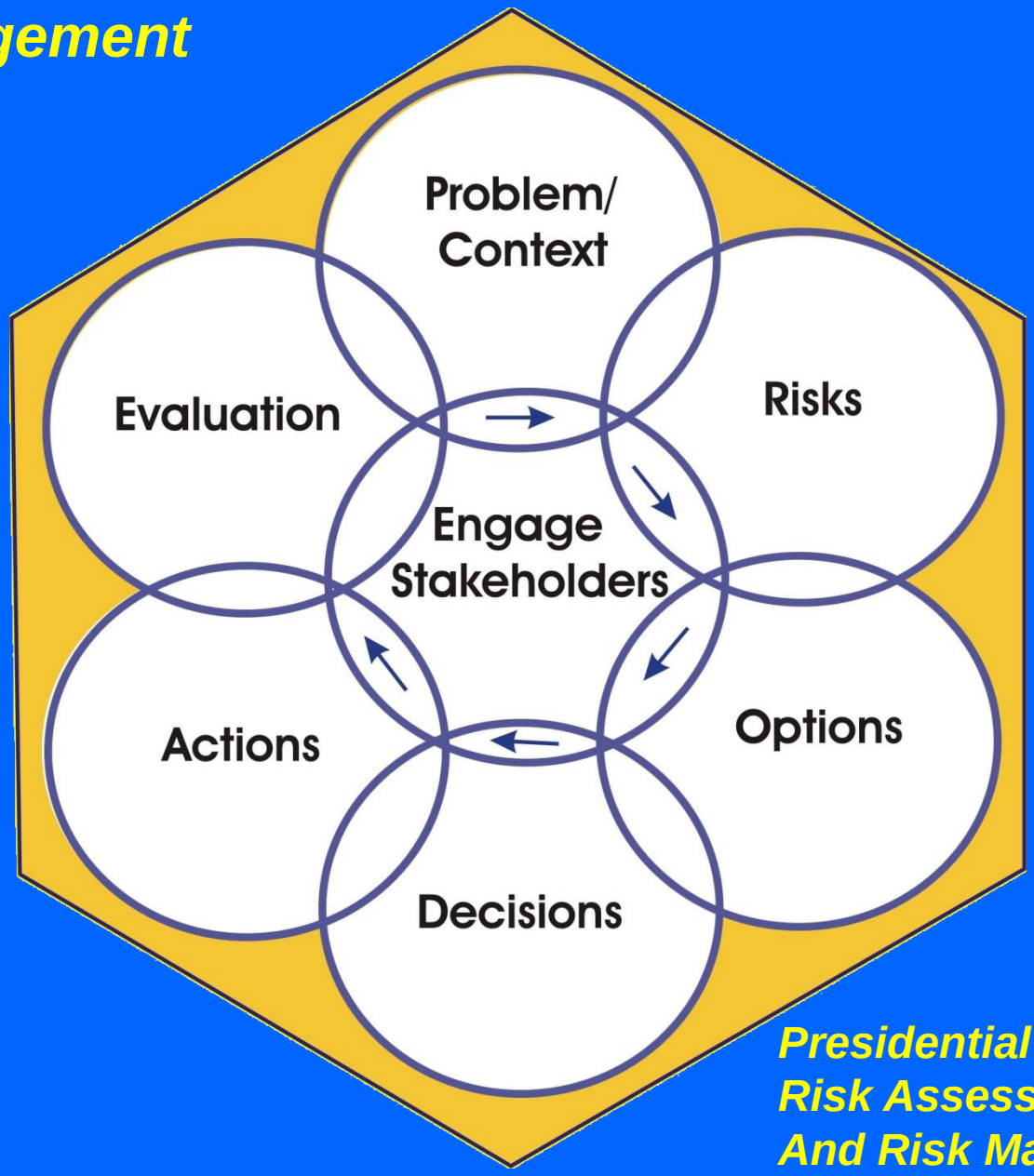


Risk Analysis



"Red Book" 1983

Framework for Environmental Health Risk Management



Presidential Commission on Risk Assessment And Risk Management

Iterative Approach to Environmental Risk Assessment

Screening level or First Tier

Initial techniques are simple, inexpensive and conservative

Higher Tiers

More sophisticated techniques are reserved for cases where some level of risk is identified using the initial screening techniques

Risk Assessments in Regulation

- ***Standard setting***
  - ***Acceptable Daily Intake (ADI)***
  - ***Maximum Level of Residue (MRL)***
  - ***Permissible Exposure Limits (PEL)***
  - ***Maximum Contaminant Levels (MCL)***
  - ***Food Additives***
- ***Aggregate and Cumulative Exposures in Pesticides***
- ***Risk Ranking***

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Dietary Exposure

Consumption of food containing one or more common mechanism of action pesticide residues

Consumption of one or more foods containing residues of a particular pesticide

Estimation of Pesticide Risk

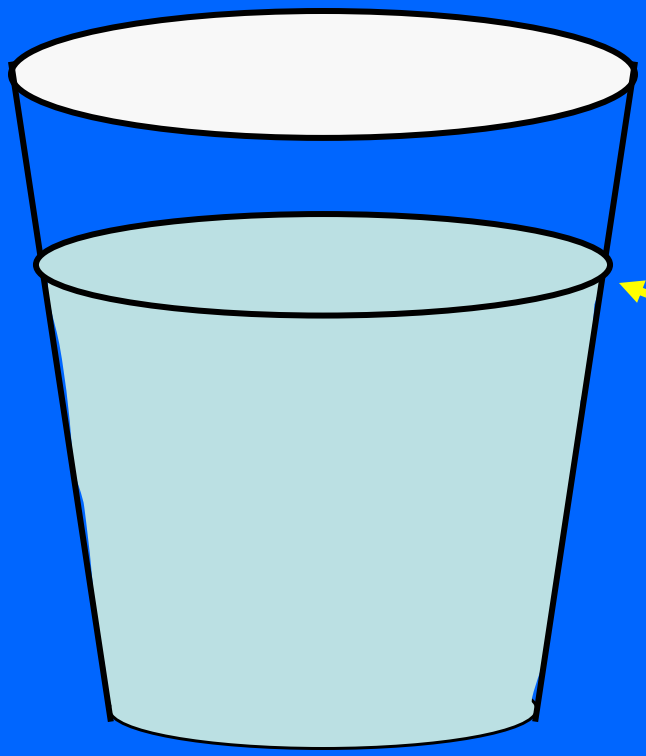
$$\text{“Risk Cup” \% Population Adjusted Dose (mg/kg)} = \frac{\text{Exposure}}{\text{Population Adjusted Dose}}$$

Risk Cup > 100% Unacceptable Risk – Cancellation of Uses
Risk Cup < 100% Acceptable Risk – New Uses Allowed

$$\text{Exposure (mg/kg)} = \Sigma\,(\text{Dietary} + \text{Drinking Water} + \text{Residential Exposure})$$

$$\text{Population Adjusted Dose (mg/kg)} = \frac{\text{Benchmark Toxicity Dose (from animal tests)}}{\text{Safety Factors } (10 * 10 * 10)}$$

New Uses Allowed until Risk Cup is Full

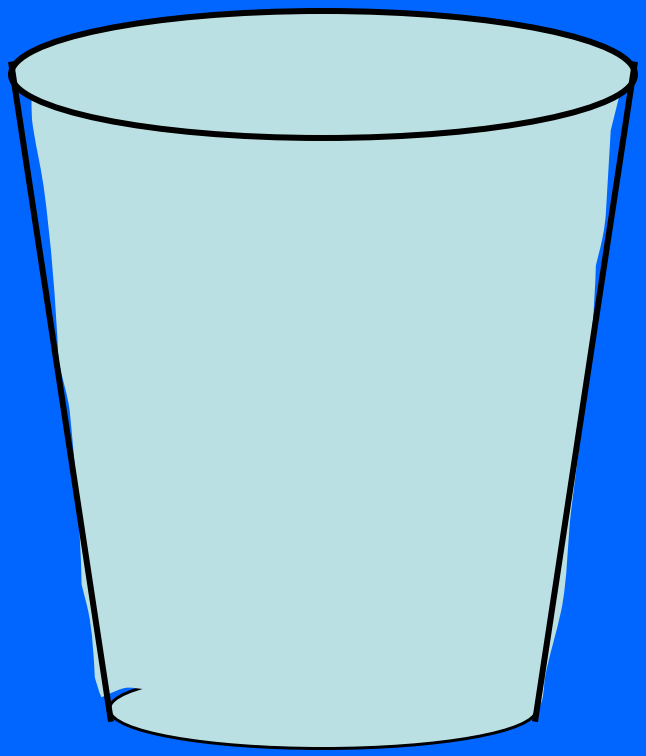


Population Adjusted Dose (mg/kg)

Exposure from All Uses (mg/kg)

Risk Cup

No New Uses Allowed Unless Some Uses Are Removed



Risk Cup

Population Adjusted Dose (mg/kg)

Exposure from All Uses (mg/kg)

Outline of US EPA's current assessment system

- Inputs
  - 2 days of dietary recall per food survey respondent (NHANES)
  - Pesticide residue concentrations on commodities
  - Processing and cooking factors for pesticide/commodity combinations
  - Specified population of interest
  - Specified number of model iterations
- Acute One-Day Exposure Estimate
  - Each iteration generates a set of dietary exposures, using all dietary recalls – both days- for all respondents from the specified population
  - Residues are selected from distributions of actual residues
  - Daily exposure is calculated considering respondent body weight
  - Risk metric is calculated by comparing the exposure estimates to a toxicological value

Dietary Exposure Calculation – General Form

Survey of daily consumption of food (NHANES)

Translation of food to agricultural product (FCID)

List of agricultural products consumed daily

Pesticide residues on agricultural products (PDP)

$$\text{Exposure} = \frac{(\text{Amount of agricultural product consumed} \times \text{pesticide residue in agricultural product})}{\text{body weight}}$$

Pesticide Residues

Pesticide sprayed on an agricultural commodity

Commodity is processed Into another form

COMPOSITE PDP DATA

Commodity is available to consumer as a processed food

Commodity is available to consumer as raw agricultural commodity

SINGLE SERVING PDP DATA

Commodity may be cooked, canned, frozen, boiled, concentrated, or otherwise manipulated or may remain raw

RESIDUE – PDP adjusted by PROCESSING OR COOKING FACTORS

Food Consumption

Consumer eats some amount of a food containing an agricultural commodity

RT-30 FOOD_CODE

The food is a raw agricultural commodity

The food contains several raw or processed agricultural commodities

The food's recipe specifies the relative proportions of agricultural commodities in the food

FCCOMMREV

COM_CODE & COM_AMT

FCCOMMREV

Recipe translation to agricultural commodity and processing/cooking status

FCCOMMREV COM_CODE & FOODFORM

Diet for One Year Old Female; 8.18 kg body weight

TIME	FOODCODE	DESCRIPTION	AMOUNT
1000	57214000	~Frosted Mini-Wheats~	53
1000	11111000	~Milk, cow's, fluid, whole~	183
1200	14301010	~Cheese, cream~	29
1200	51109100	~Bread, pita~	104.72
1200	64100110	~Fruit juice blend, 100% juice, with added Vitamin C~	210.94
1430	57417000	~Shredded Wheat, 100%~	25
1430	11111000	~Milk, cow's, fluid, whole~	122
1600	75233011	~Squash, summer, cooked, from fresh, fat not added	90
1600	56101030	~Macaroni, cooked, fat added in cooking~	72.5
1600	75217400	~Garlic, cooked~	0.25
1600	31105000	~Egg, whole, fried~	17.25
1600	51109100	~Bread, pita~	104.72
1600	14108010	~Cheese, Parmesan, dry grated~	6.25
1600	75233021	~Squash, summer, cooked, from fresh, fat added in cooking~	354.38
2000	53206020	~Cookie, chocolate chip, made from home recipe	20
2000	11111000	~Milk, cow's, fluid, whole~	244

Calculation of Commodity Specific Dietary Exposure

$$\text{Dietary Exposure (mg pesticide/kg b.w.)} = \frac{\text{Pesticide Concentration on Agric. Commodity (mg Pesticide/kg Commodity)} \times \text{Amount of Commodity Consumed (g)}}{\text{Body Weight (kg)} \times \frac{1000\text{ g Commodity}}{1\text{ kg Commodity}}}$$

Daily Dietary Exposure = Sum of exposure over all agricultural products

Screening level

WHICH MAKES THE BEST METRIC?

- Upper end per capita consumption
- Average per capita consumption
- Eaters only upper end per capita consumption
- Eaters only average per capita consumption

Upper Tier Dietary Exposure Assessment

Probabilistic Assessment

Estimates Exposures over 24 hour period

DEEM-FCID software used

Combines consumption data from CSFII/NHANES with residue data from the PDP

Aggregate Exposure Assessment

Exposure assessment based on:

Exposure from dietary, water, and residential non-occupational pathways

Residential non-occupational pathways include dermal, inhalation and non-dietary oral

Dietary exposure calculated by DEEM-FCID

Water, residential and non-dietary oral exposure calculated by CALENDEX-FCID

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Populations of Interest

General Population

Children 1-2 years old

Children 3-5 years old

Adults 29 to 50

Adults over 50

Residue data used in the Dietary Exposure

Residues from PDP Data for OPP in mushrooms

Residues from 2002 PDP data shown in this example

Residue values adjusted by processing factors for some types of processed foods

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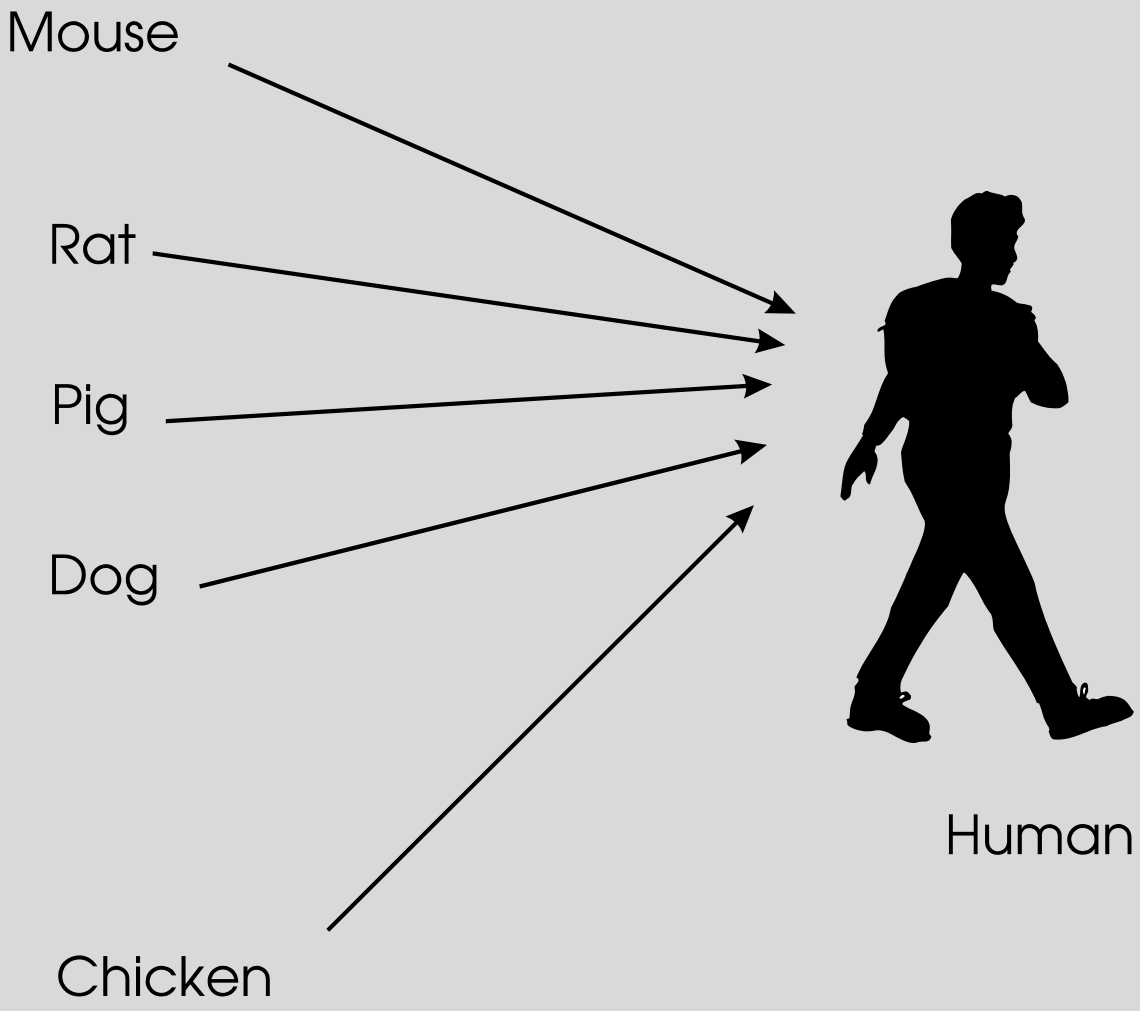
Extrapolation of Laboratory Data to Human Health



Calculation of a RfD

$$RfD = \frac{NOAEL}{\prod_{i=1}^{n} UF_i}$$

NOAEL - No Observed Adverse Effect Level

UF - Uncertainty Factor

Toxicological Data

- Chronic Reference Dose (cRfD)
- No Acute Reference Dose (aRfD)
- No Observed Effect Level
  - Rat study dietary exposure
  - Study used by California EPA, Division of Pesticide Regulation

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Dietary Exposure Values
Exposures > Threshold Are of Concern

Hypothetical exposure from commodity X (% of aRfD)

	95th%	99th%	99.9th%
US Pop	0	0.06	0.49
Infants	0	0.00	0.08
Children 1-6	0	0.04	0.63
Children 1-2	0	0.07	0.81
Children 3-5	0	0.04	0.57

0.01 mg/kg bw/day Threshold

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